

**We Claim:**

1. A method for detecting cervical carcinomas, cervical intraepithelial neoplasias or cervical carcinomas in-situ from a solubilized sample of a human subject, the method comprises the steps of:
  - 5 (a) obtaining a cervical body sample from a human subject,
  - (b) solubilizing the cervical body sample in a lysis buffer, and
  - (c) determining the overexpression of cyclin dependent kinase inhibitor p16 in the solubilized cervical sample by comparing the level of cyclin dependent kinase inhibitor p16 within said solubilized cervical sample with the level present in a solubilized healthy human cervical sample.
- 10 2. The method according to Claim 1, wherein the level of cyclin dependent kinase inhibitor p16 in the healthy human cervical body sample is provided as a predetermined value to set up a threshold for the detection procedure.
- 15 3. The method according to Claim 1, wherein the level of cyclin dependent kinase inhibitor p16 in a healthy human cervical sample is determined from a standardized sample solution, or from a representative number of healthy human cervical samples.
- 20 4. The method according to Claim 3, and wherein the determination of the level of cyclin dependent kinase inhibitor p16 in a healthy human cervical sample is carried out:
  - a. in the course of the detection procedure,
  - b. upon calibration of the detection system,
  - c. once for each lot of detection reagents, or
  - d. as a standard value for the detection method.
- 25 5. The method according to Claim 1, wherein the cervical body sample is swab, smear, aspirate, biopsy, preserved cytological specimen, histological specimen, fixed cell preparation or fixed tissue preparation.

6. The method according to Claim 1, wherein the cervical body sample is solubilized
  - a. immediately after obtaining the sample,
  - b. after storage and/or transport in a storage buffer, or
  - c. after transport in a transportation buffer.
- 5      7. An in-vitro diagnostic device comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed on solid carriers, for detecting p16 in a solubilized sample.
8. The in-vitro diagnostic device according to Claim 7, which is selected from the group consisting of:
  - 10      a. an ELISA device comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed to ELISA plates, ELISA stripes or ELISA wells;
  - b. a lateral flow test device, comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed to test strips, colloidal gold particles or latex particles;
  - 15      c. a flow through assay device, comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed to a porous member, or to the surface of capillaries;
  - d. a latex agglutination assay device, comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed to latex particles;
  - 20      e. an immunoassay device, comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed to beads or membranes; and
  - f. an immunoassay device, comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed to microspheres.
9. A test kit for determining the level of cyclin dependent kinase inhibitor p16 comprising antibodies directed against cyclin dependent kinase inhibitor p16 and a lysis buffer for solubilization of a body sample.
- 25      10. The test kit according to Claim 9, wherein the lysis buffer comprises at least one composition selected from the group consisting of chaotropic agents, anionic detergents,

cationic detergents, non-ionic detergents, amphoteric detergents, and alkaline compositions.

11. The test kit according to Claim 9, wherein the lysis buffer comprises at least one composition selected from the group consisting of a proteinase inhibitor, a DNase inhibitor, and an RNase inhibitor.
12. The test kit according to Claim 11, wherein the proteinase inhibitor is selected from the group consisting of inhibitors to serine proteinases, inhibitors to cysteine proteinases, inhibitors to aspartic proteinases, inhibitors to metallo proteinases, inhibitors to acidic proteinases, inhibitors to neutral proteinases, and inhibitors to alkaline proteinases.
13. The test kit according to Claim 9, wherein the lysis buffer comprises at least one non-ionic detergent and at least one proteinase inhibitor.
14. The test kit according to Claim 13, wherein the lysis buffer contains Triton X-100 and at least one inhibitor of serine proteases.
15. The test kit according to Claim 9, further comprising at least one marker molecule for carrying out a positive control reactions, reagents and buffers commonly used for carrying out the detection reaction.
16. The test kit according to Claim 9, further comprising a recombinant p16 protein, fragments thereof or peptides derived from p16 as marker molecules for carrying out a positive control reaction.
17. A test kit comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed on solid carriers, for detecting p16 in a solubilized sample.
18. The test kit according to Claim 17, which is selected from the group consisting of:
  - a. an ELISA kit comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed to ELISA plates, ELISA stripes or ELISA wells;
  - b. a lateral flow test kit, comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed to test strips, colloidal gold particles or latex particles;

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- c. a flow through assay kit, comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed to a porous member, or to the surface of capillaries;
- d. a latex agglutination assay kit, comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed to latex particles;
- e. an immunoassay kit, comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed to beads or membranes; and
- f. an immunoassay kit, comprising antibodies directed against cyclin dependent kinase inhibitor p16 fixed to microspheres.